My third question relates to the clinical indications for the device. There is a broad spectrum of patients with type IIIb MR with regard to the severity of mitral regurgitation and the degree of left ventricular dilatation. Which patients within this spectrum do you feel are likely to have a successful, durable outcome with this device? Specifically, do you believe that it will work as sole therapy for patients with severe MR and dilated ventricles or do you see it as an adjunct to annuloplasty in these patients?

Dr McCarthy. First, we assess carefully all of the changes that we see regarding durability. One explanation for some of the differences in measurements—which, by the way, were only about 3 mm—is that some of those measurements were made in the acute setting with the chest open, versus later measurements with the chest closed. So there are certainly differences in loading conditions. Also, measurements are influenced by the difference in echo techniques in that the measurement of the annular area was by short axis, the measurement of the septolateral by long axis, and the commissure-to-commissure measurement by 2-chamber views. So it is hard in 2-D echoes to really recreate the total annular area and correlate it to the other 2 measurements because of the different views. Furthermore, this is a pacing model of heart failure that we had developed a few years ago, and there is ongoing pacing at a rate of 190 beats per minute. So we expect that there would be some continued remodeling during that time, which may account for some of the small changes. Nevertheless, durability is the most important issue for the clinical trials.

In terms of the technique, I completely agree that anatomic measurements, including coaptation depth and length, would probably be a much more accurate way to judge how to place the device than merely by interpreting color Doppler echo. This is certainly something that will be looked at carefully in the clinical cases.

In terms of the clinical indications, I don't know yet exactly what role this is going to have. Coapsys just recently began a randomized clinical trial in the United States with groups of patients undergoing coronary artery bypass grafting (CABG) with ring annuloplasty, patients undergoing CABG alone, and CABG with the Coapsys device. So we will be looking at how this holds up in patients with ischemic cardiomyopathy and then we can determine the proper role for Coapsys.